REMARKS

Claims 77-86, 88-95, 97-101, 103-123, 125-131 and 133-155 were pending in the present application.

The Applicant thanks the Examiner for the opportunity to discuss the outstanding action during the recent telephonic interview with the Examiner. The Applicant further thanks the Examiner for the timely issuance of the Interview Summary.

Clarification of Filing of Continuing Prosecution Application (CPA)

The Applicant would like to note that the outstanding Office Action mistakenly referred to the continuing application filed in the present application as a "Request for Continued Examination (RCE)", when in fact, as noted by the Examiner during telephonic interview on November 19, 2002, the present application was filed as a "Continuing Prosecution Application (CPA)".

Rejections under double patenting

Claims 77-86, 88-95, 97-101, 103-123, 125-131 and 133-155 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 14-21, 23-28, 30-33, 35-44 and 46 of U.S. Patent No. 6,008,202.

A terminal disclaimer with respect to U.S. Patent No. 6,008,202 is being filed herewith.

Accordingly, the Applicant respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 77-86, 88-95, 97-101, 103-123, 125-131 and 133-155 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not reasonably providing enablement for any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

In response, the Applicant would like to make the following points.

Claims 77-86, 88-95, 97-101, 103, 107-112, 137-141, and 154-155 are directed to the claimed complex and methods of producing the complex. Applicants assert that these compositions, and methods of making them, are fully enabled by the specification as filed.

The Applicant also notes that the claims, with respect to the composition, method of producing the complex and method of delivering the complex (claims 104-106, 113-131, 133-136, and 142-153), that the claimed complex as described by the specification is not intended in and of itself to be a "drug". It is important to note that the claimed complexes (and those used in the produced by, and used in, the claimed methods) serve as delivery vehicles for the "drug" payload, and such payloads may be intended as therapeutic agents *or* diagnostic agents, both encompassed within the term "drug". The Applicants assert that these claims are therefore enabled by the specification as filed.

In addition to the *in vivo* example of cancer therapy where the nucleic acid is an E1A gene in Example 18, the specification as filed gives a number of Examples in which reporter genes (*e.g.,* luciferase, choramphenicol acetyl transferase), whose use for diagnostic purposes is well known in the art, are successfully *delivered* to a variety of cell types (*e.g.*, chinese hampster ovary (CHO), BHK, mouse lung cells (MLC), 293, BL6, C3, SKOV-3 human ovarian carcinoma, HeLa), both *in vitro* and *in vivo*. See, *e.g.,* Examples 4, 5, 7 (*in vivo*), 12 (*in vivo*), and 17 (*in vivo*). It is also known in the art that successful transfection of reporter genes under a given set of conditions is indicative of successful transfection (i.e. *delivery to cells*) of nucleic acids in general under similar conditions.

In the outstanding Office Action the Examiner asserts that the complexes as taught in the specification are too large for successful uptake by cells. However, the Applicant would like to point out that the species taught in, for example, Perales (1994a, b), Schlepper-Schafer (1986), do not contain cationic fusogenic lipids, as do those complexes described in the specification. Thus, the complexes as claimed are not restricted to delivery of the nucleic acid payload via an

endocytotic pathway, and therefore differ from the species described in the cited references. As is known in the art, where transfection is already successful, as proved by the successful incorporation of reporter genes into the cells described in the Examples, the addition of a targeting factor is an additive effect to transfection efficiency.

In light of the above discussion, the Applicant requests withdrawal of the rejection of claims 77-86, 88-95, 97-101, 103-123, 125-131 and 133-155.

CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 226272002201.

Respectfully submitted,

Dated: December 9, 2002 By: _____

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